Application No. 09/972,425
Attorney's Docket No. 033053-025

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Kenneth C. Cundy, et al.

Application No.: 09/972,425

Filed: October 5, 2001

For: Bile-Acid Derived Compounds for Providing Sustained Systemic Concentrations of Drugs After Oral Administration

Group Art Unit: 1614

Examiner: Unassigned

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

[x] No additional fee for submission of an IDS is required.

[ ] The fee of IDS as set forth in 37 C.F.R. § 1.17(p) is also enclosed.

[ ] A certification under 37 C.F.R. § 1.97(e) is also enclosed.

[ ] A certification under 37 C.F.R. § 1.97(e), and the fee of IDS as set forth in 37 C.F.R. § 1.17(p) are also enclosed.

[ ] Charge $_____ to Deposit Account No. 02-4800 for the fee due.

[ ] A check in the amount of $_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
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Date: January 29, 2002

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited below is enclosed:

U.S. Patents/Applications:

4,024,175	5/17/77	Satzinger	*Cyclic Amino Acids*
5,462,933	10/31/95	Kramer	*Modified Bile Acid Conjugates, and Their Use as Pharmaceuticals*
5,541,348	7/30/96	Ayra	*Bile Acids for Biological and Chemical Applications and Processes for the Production Thereof*
5,563,175	10/8/96	Silverman	*GABA and L-glutamic Acid Analogs for Anti-Seizure Treatment*
5,646,272	7/8/97	Kramer	*Bile Acid Conjugates of Proline Hydroxylase Inhibitors*
5,668,126	9/16/97	Kramer	*Bile Acid Derivatives, Processes for Their Preparation and Use as Pharmaceuticals*

5,684,018	11/4/97	Alexander	*Acyloxyisopropyl Carbamates as Prodrugs for Amine Drugs*
6,020,370	2/1/00	Horwell	*Bridged Cyclic Amino Acids as Pharmaceutical Agents*
6,028,214	2/22/00	Silverman	*GABA and L-glutamine Acid Analogs for Anti-Seizure Treatment*
6,103,932	8/15/00	Horwell	*Substituted Cyclic Amino Acids as Pharmaceutical Agents*
6,117,906	9/12/00	Silverman	*GABA and L-glutamine Acid Analogs for Anti-Seizure Treatment*

Foreign Patents:

WO 92/09560	Published: 6/11/92	*GABA and L-glutamic Acid Analogs for Antiseizure Treatment*
WO 93/23383	Published: 11/25/93	*GABA and L-Glutamic Acid Analogs for Antiseizure Treatment*
WO 97/29101	Published: 8/14/97	*Novel Cyclic Amino Acids as Pharmaceutical Agents*
WO 99/61424	Published: 12/2/99	*Conformationally Constrained Amino Acid Compounds Having Affinity for the Alpha2Delta Subunit of a Calcium Channel.*
WO 00/31020	Published: 6/2/00	*Improved Gamma Amino Butyric Acid Analogs*
WO 00/50027	Published: 8/31/00	*Gabapentin Derivative for Preventing and Treating Visceral Pain.*
WO 99/21824	Published: 5/6/99	*Cyclic Amino Acids and Derivatives Thereof Useful as Pharmaceutical Agents*

WO 97/33858 Published: 9/18/97		*Novel Substituted Cyclic Amino Acids as Pharmaceutical Agents*
WO 97/33859 Published: 9/18/97		*Novel Bridged Cyclic Amino Acids As Pharmaceutical Agents*
WO 98/17627 Published: 4/30/98		*Substituted Gamma Aminobutyric Acids as Pharmaceutical Agents*
WO 99/31057 Published: 6/24/99		*4(3)Substituted-4(3)-Aminomethyl-(Thio)Pyran or -Piperidine Derivatives (=Gabapentin Analogues), Their Preparation and Their Use in the Treatment of Neurological Disorders.*
WO 99/31074 Published: 6/24/99		*Novel Amines as Pharmaceutical Agents*
WO 99/31075 Published: 6/24/99		*1-Substituted-1-Aminomethyl-Cycloalkane Derivatives (=Gabapentin Analogues), Their Preparation and Their Use in the Treatment of Neurological Disorders.*
WO 00/15611 Published: 3/23/00		*Branched Alkyl Pyrrolidine-3-Carboxylic Acids*
WO 00/23067 Published: 4/27/00		*Method for the Treatment of Mania and Bipolar Disorder*
WO 99/08671 Published		
European Patent No. 0 272 462 B1	6/29/88	*Process for Preparing Ursodeoxycholic Acid Derivatives and Their Inorganic and Organic Salts Having Therapeutic Activity*

Articles:

Baringhaus, K.H., et al., Substrate specificity of the ileal and hepatic Na^+ / bile acid cotransporters of the rabbit. II. A reliable 3D QSAR pharmacophore model for the ileal Na^+ / bile acid cotransporter,. *J. Lipid Res.* **1999**, *40*, pp. 2158-2168.

Batta, et al., *J. Lipid Res.*, **1991**, *32*, pp. 977-983.

Bryans, J. S., et al., 3-Substituted GABA analogs with central nervous system activity: a review., *Med. Res. Rev.* **1999**, 19, pp. 149-177.

Bundgaard, H., in *Design of Prodrugs* (Bundgaard, H. Ed.), Elsevier Science B.V., **1985**, pp. 1-92.

Ho, N. F. H., Utilizing bile acid carrier mechanisms to enhance liver and small intestine absorption. *Ann. N. Y. Acad. Sci.*, **1987**, *507*, pp. 315-329.

Jezyk, N., et al., Transport of pregabalin in rat intestine and Caco-2 monolayers, *Pharm. Res*,. **1999**, *16*, pp. 519-526.

Kagedahl, M., Use of the intestinal bile acid transporter for the uptake of cholic acid conjugates with HIV-1 protease inhibitory activity, *Pharm. Res.*, **1997**, *14*, pp. 176-180.

Kim, D.C., et al., Evaluation of bile acid transporter in enhancing intestinal permeability of renin-inhibitory peptides, *J. Drug Targeting*, **1993**, *1*, pp. 347-359.

Kramer, W., et al., Liver-specific drug targeting by coupling to bile acids, *J. Biol. Chem*,. **1992**, 267, pp. 18598-18604.

Kramer, W., et al., Intestinal absorption of peptides by coupling to bile acids, *J. Biol. Chem.*, **1994a**, *269*, pp. 10621-10627.

Kramer, W., et al., Bile acid derived HMG-CoA reductase inhibitors, *Biochim. Biophys. Acta*, **1994b**, 1227, pp. 137-154.

Kramer, W., Substrate specificity of the ileal and hepatic Na^+ / bile acid cotransporters of the rabbit. Transport studies with membrane vesicles and cell lines expressing the cloned transporters, *J. Lipid Res.*, **1999**, 40, pp. 1604-1617.

Kullak-Ublick, G. A., et al., Hepatobiliary transport, *J. Hepatology*, **2000**, *32 (Suppl. 1)*, 3-18.

Navia, M. A.; et al., Design principles for orally bioavailable drugs, *Drug Discovery Today*, **1996**, *1*, 179-189.

Petzinger, E., et al. , Hepatobiliary transport of hepatic 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors conjugated with bile acids., *Hepatology*, **1995**, 22, pp. 1801-1811.

Swaan, P. W., et al., Use of the intestinal and hepatic bile acid transporters for drug delivery, *Adv. Drug Delivery Rev.*, **1996**, 20, pp. 59-82.

Tsjui, A., Carrier-mediated intestinal transport of drugs, *Pharm. Res.*, **1996**, 13, pp. 963-977.

The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

To assist the Examiner, the documents are also listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

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